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Chlorpropham/018301/PIN/NIP, Inc. DACO 7.4.1/OPPTS 860.1500/OECD II

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3 Fumigation Trial — Potato

Primary Evaluator	William D. Wassell, Chemist Registration Action Branch (RAB1) Health Effects Division (HED, 7509P)	Date: 31-JAN-2008
Approved by	George F. Kramer, Ph.D., Senior Chemist RAB1/HED (7509P)	Date: 31-JAN-2008

STUDY REPORT:

47166001; de Weerd, J. (2005) Magnitude of Chlorpropham Residue in Fresh and Processed Potatoes after Two Post-Harvest Aerosol 165% Applications. Study Number: DCLGLP R05-005. Unpublished study prepared by PIN/NIP, Inc., DiChlor Research Laboratory. 83 p.

EXECUTIVE SUMMARY:

PIN/NIP, Inc. has submitted data for the use of the active ingredient (ai) chlorpropham on potatoes. A single fumigation trial was performed at a commercial potato storage facility. Approximately 5.5 million pounds (lb) of potatoes were treated twice with solid formulated chlorpropham (PIN NIP 98% Chlorpropham, EPA Reg. No. 65726-3) at the rate of 0.0167 lb ai per 1,000 lb potato. The second application was 47 days following the first application. The total application rate was 0.0550 lb per 1,000 lb potatoes.

The applications were made using standard aerosol generating equipment typically used for this type of application. The application involved generation of the chlorpropham aerosol and circulation of the aerosol by the storage facility ventilation system. The ventilation system of a commercial potato storage facility, pushes air from beneath the potato pile so that it may flow upward. Tuber samples were collected just prior to treatment, and at intervals after both the first and second treatments. Samples were collected from three different pile depths.

Chlorpropham residues were determined in raw potato peel, pulp, and chips. A previous processing study (MRID 46151701) indicated that the highest residues and greatest potential for concentration of residues were consistently in/on potato chips.

Samples of potato peel, pulp, and chips were analyzed for residues of chlorpropham using a high-performance liquid chromatograph with an ultraviolet/visible light detector (HPLC/UV) method. This method was previously submitted to the Agency (MRID 46151702). Residues in whole potatoes were calculated by summing the actual residues quantified in the potato peel and pulp and dividing by the whole potato weight. The registrant reported the method has a limit of quantification (LOQ) of 0.05 ppm; however, the method was concurrently validated to a limit of 2 ppm chlorpropham in/on potatoes and to 0.5 ppm in/on potato chips. Adequate method recoveries were observed from whole potato samples fortified at 2 and 20 ppm and from chip samples fortified at 0.5 and 2 ppm. The limit of detection (LOD) was not reported. This method

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is adequate for data collection based on acceptable method validation and concurrent recovery data.

Residues of chlorpropham ranged from 3.97 to 5.73 ppm in potato tubers collected 1 to 47 days following a fumigant application at 0.0275 lb ai/1000 lb potato. Additionally, residues of chlorpropham ranged from 11.2 to 14.8 ppm in potato tubers collected 1 to 92 days following the two fumigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato. Apparent residues of chlorpropham were 0.032 ppm in/on one sample of untreated potato. Residue levels remained relatively stable as the time between treatment and sampling was increased. Residues of chlorpropham were 0.31 and 0.66 ppm in potato chips collected 30 and 92 days, respectively, following the two fumigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato. The maximum storage interval from harvest to analysis was 20 days. Thus, storage stability data for residues of chlorpropham in/on potato are not required.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

The submitted potato residue data are classified as scientifically acceptable under the conditions and parameters used in the study. The acceptability of this study for regulatory purposes is addressed in the forthcoming summary document (DP Number 341866).

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP) Statement, Quality Assurance, and Data Confidentiality statements were provided. Minor deviations from regulatory requirements were reported. However, these deviations did not have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Chlorpropham is a plant-growth inhibitor used to inhibit sprouting in potatoes and reduce *Botrytis* infection in Easter lilies as well as assist in their floral bud removal. Chlorpropham may be applied by aerosol generator, mist blower, sprayer, low pressure ground boom, and foaming apparatus. The Chlorpropham Reregistration Eligibility Document (RED) was issued 10/96, and the Report of FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for chlorpropham was issued 9/02. Chlorpropham is formulated as a ready-to-use (RTU) solution.

Tolerances are established (40 CFR §180.181) for residues of chlorpropham and its metabolite 1-hydroxy-2-propyl 3'-chlorocarbanilate in/on potatoes at 50 ppm. However, HED has requested the level of the tolerance be revised to 30 ppm for residues of chlorpropham, *per se*.

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Table A.1. Nomenclature of Chlo	orpropham.
Compound	O CH ₃
Common name	Chlorpropham
Company experimental names	CIPC
IUPAC name	isopropyl 3-chlorocarbanilate
CAS name	1-methylethyl (3-chlorophenyl)carbamate
CAS#	101-21-3
End-use products/EPs	PIN NIP 98% Chlorpropham, EPA Reg. No. 65726-3

Parameter	Value	Reference		
Melting range	38-40°C			
рН	5.62-5.66			
Density at 24°C	1.17 g/cm ³			
Water solubility	89 ppm (25°C)			
Solvent solubility (g/100 mL)	Soluble in ethyl and isopropyl alcohols, ketones, and aromatic solvents.	Chlorpropham RED, 10/96		
Vapor pressure (Pa) at 25°C	2.46 x 10 ⁻² Pa at 25°C			
Dissociation constant (pK _a)	13.8 in 19% ethanol/water (v/v) at 20°C	1		
Octanol/water partition coefficient (Kow)	3.47 at 25°C	1		
UV/visible absorption spectrum	NA	1		

NA = information is not available.



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B. EXPERIMENTAL DESIGN

B.1. Study Site Information

	Soil characteristics			. i	Meteorological data		
Trial Identification (City, State; Year)	Туре	%OM¹	pН	CEC ²	Rainfall from first application to sampling (inches)	Overall temperature range (°F)	
01 (Rexburg, ID; 2005)		Informa	ation no	t applicabl	e to post-harvest storage t	reatments.	

¹%OM = percent organic matter.

Storage facility temperature was maintained at 4.5 to 7°C.

Table B.1.2. Study U	se Patte	rn.				
Trial Identification (City, State; Year)		Application				
	EP ¹	Method; Timing	Rate (lb ai/ 1000lb potatoes)	RTI ² (days)	Total Rate (lb ai/ 1000lb potatoes)	Tank Mix Adjuvants
01	98%	Post-harvest via thermal fogger connected to the ventilation system.	0.0275		0.055	
(Rexburg, ID; 2005)	RTU	Post-harvest via thermal fogger connected to the ventilation system.	0.0275	47	0.055	None

¹ EP = End-use Product, PIN NIP 98% Chlorpropham (EPA Reg. No. 65726-3).

B.2. Sample Handling and Preparation

Single samples of potato tubers (10 potatoes per sample) from the top, middle, and bottom of the potato pile were collected 1 days prior to treatment (control) and 1, 15, and 47 days after the first treatment, and 15, 30, 60, and 92 days after the second treatment. Collected samples were bagged and shipped within 24 hours of collection to DiChlor Research Laboratory (Meridian, ID) for residue analysis. At the laboratory, samples were stored in mechanically cooled storage bins at 4°C.

To produce potato chips, whole potatoes were washed with water, peeled and cut into slices using a food-slicer. The slices were rinsed with water and fried at approximately 350°F (176°C) in vegetable oil for 2.5 minutes. A sample consisted of the slices from an individual tuber and were collected in separate jars.

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²CEC = cation-exchange capacity.

² RTI = Retreatment Interval.



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B.3. Analytical Methodology

Potato peel and pulp samples were separately analyzed for residues of chlorpropham using an HPLC/UV method. Residues in whole potatoes were calculated by summing the actual residues quantified in the potato peel and pulp. For a complete description of the method refer to the method validation study (DER for MRID 46151702). A brief description of the method follows.

To simulate consumer practices, whole potatoes were washed with water, and peeled. Peel, pulp and chip samples were blended with reagent grade alcohol (90-91% ethanol denatured with 5% isopropyl alcohol and 4-5% methanol; 100% or 80% in water), warmed to 50°C for 30 minutes in a water bath, and shaken for 20 minutes at ambient temperatures. The extract was filtered for HPLC/UV analysis. The LOQ was reported to be 0.05 ppm. However, the method was validated to a limit of 2 ppm for peel and pulp, and 0.5 ppm for chips. The LOD was not specified.

Untreated samples (collected prior to treatment) were spiked with chlorpropham for concurrent method recoveries, by trickling a chlorpropham solution onto the outer peel of the whole potato. After spiking, the whole potato was separated into peel and pulp for analysis, and chlorpropham recoveries from whole potato were calculated from the residues in the peel and pulp. Recovery of chlorpropham via the method from potato peel and pulp samples ranged from 85 to 103%, and for potato chip samples ranged from 76 to 104%.

C. RESULTS AND DISCUSSION

A single trial was performed at a commercial potato storage facility. Approximately 5.5 million lb of potatoes were treated twice with solid formulated chlorpropham (PIN NIP 98% Chlorpropham, EPA Reg. No. 65726-3) at the rate of 0.0167 lb ai per 1,000 lb potato. The second application was 47 days following the first application. The total application rate was 0.0550 lb per 1,000 lb potatoes. The applications were made using standard aerosol generating equipment typically used for this type of application. The application involved generation of the chlorpropham aerosol and circulation of the aerosol by the storage facility ventilation system. The ventilation system of a commercial potato storage facility, pushes air from beneath the potato pile so that it may flow upward. Tuber samples were collected just prior to treatment, and at specific intervals after both the first and second treatments. Samples were collected from three different pile depths.

Samples of potato peel, pulp, and chips were analyzed for residues of chlorpropham using an HPLC/UV method. This method was previously submitted to the Agency (MRID 46151702). Residues in whole potatoes were calculated by summing the actual residues quantified in the potato peel and pulp and dividing by the whole potato weight. The registrant reported the method has a LOQ as 0.05 ppm; however, the method was concurrently validated to a limit of 2 ppm chlorpropham in/on potatoes and to 0.5 ppm in/on potato chips. Adequate method recoveries were observed from whole potato samples fortified at 2 and 20 ppm and from chip samples fortified at 0.5 and 2 ppm. The LOD was not reported. This method is adequate for data collection based on acceptable concurrent recovery data. Concurrent recovery data are presented

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in Table C.1.

Residues of chlorpropham ranged from 3.97 to 5.73 ppm in potato tubers collected 1 to 47 days following a furnigant application at 0.0275 lb ai/1000 lb potato. Additionally, residues of chlorpropham ranged from 11.2 to 14.8 ppm in potato tubers collected 1 to 92 days following the two furnigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato. Apparent residues of chlorpropham were 0.032 ppm in/on one sample of untreated potato. Residue levels remained relatively stable as the time between treatment and sampling was increased. Residues of chlorpropham were 0.31 and 0.66 ppm in potato chips collected 30 and 92 days, respectively, following the two furnigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato. Residue data from the potato trial are reported in Table C.3.

The maximum storage interval from harvest to analysis was 20 days. Thus, storage stability data for residues of chlorpropham in/on potato are not required. Sample storage conditions and intervals are summarized in Table C.2.

Table C.1. Summary of Concurrent Recovery Data for Chlorpropham in/on Potato Commodities.				
Matrix	Fortification Level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
D-4-4- T-1	2.0	9	93.7, 99.1, 93.0, 103, 97.5, 92.0, 93.0, 103, 94.6	·
Potato Tuber	20.0	9	97.2, 95.2, 86.1, 99, 92.9, 85, 94.7, 100, 87.6	94.8 ± 5.2
Potato Chips	0.5	2	76.4, 86.7	00.6 + 12
	2.0	2	95.2, 104	90.6 ± 12

Table C.2. Length of Storage of Potato Commodities from Harvest to Analysis.				
Matrix	Storage Temp. (°C)	Actual Storage Duration	Interval of Demonstrated Storage Stability	
Potato Tuber	4	20 days	Not required.	
Potato Chips	4	20 days	Not required.	

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Table C.3.a. Residue D	ata for Potato Ti	ubers from Fumigation Tria	ls with Chlor	rpropham.		
Trial ID	Crop Variety	• • •	PTI ¹	Resid	lue Levels ± Std. Dev.²	
(City, State; Year)			(lb ai/ 1000 lb potatoes) (days)	(ррт)		
		(15 15 1000 15 positions)		Peel	Pulp	Whole Tuber
01 (Rexburg, ID, 2005)	Russet Burbank	0	0	0.126	0.019	0.032 ± 0.005
		0.0275	1	30.4	0.55	3.97 ± 0.61
			15	43.4	0.107	5.77 ± 1.2
	:		47	43.3	0.024	5.73± 1.1
		0.055	1	89.4	0.039	11.4 ± 2.5
			15	85.3	NA ³	11.4 ± 1.6
			30	98.7	0.065	12.8 ± 2.3
			60	113	0.185	14.8 ± 2.3
		1	92	78.9	0.200	11.2 ±2.34

¹PTI = post-treatment interval.

³ Data are not available due to chromatographic interferences.

Trial ID (City, State; Year)	Crop Variety	Total Rate (lb ai/ 1000 lb potatoes)	PTI' (days)	Residue Levels ± Std. Dev. ² (ppm)
01 (Rexburg, ID, 2005)	Russet Burbank	0.055	30	0.312 ± 0.15
		-	92	0.655 ± 0.195

¹PTI = post-treatment interval.

D. CONCLUSION

The submitted fumigant trial reflects the use of chlorpropham on stored potatoes. A single fumigation trial was performed at a commercial potato storage facility. Approximately 5.5 million lb of potatoes were treated twice with solid formulated chlorpropham (PIN NIP 98% Chlorpropham, EPA Reg. No. 65726-3) at the rate of 0.0167 lb ai per 1,000 lb potato. The second application was 47 days following the first application. The total application rate was 0.0550 lb per 1,000 lb potatoes.

Residues of chlorpropham ranged from 3.97 to 5.73 ppm in potato tubers harvested 1 to 47 days following a furnigant application at 0.028 lb ai/1000 lb potato. Additionally, residues of chlorpropham ranged from 11.2 to 14.8 ppm in potato tubers harvested 1 to 92 days following the two furnigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato. Apparent residues of chlorpropham were 0.032 ppm in/on one sample of untreated potato. Residue levels remained relatively stable as the time between treatment and sampling

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²Residue levels are the average of levels for samples taken from the top, middle and bottom of the pile. Residue levels are not corrected for residues in the controls. Std. Dev. = standard deviation.

²Residue levels are the average of levels for samples taken from the top, middle and bottom of the pile. Residue levels are not corrected for residues in the controls. Std. Dev. = standard deviation.



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was increased. Residues of chlorpropham were 0.31 and 0.66 ppm in potato chips collected 30 and 92 days, respectively, following the two furnigant applications at 0.0275 lb ai/1000 lb potato for a total rate of 0.055 lb ai/1000 lb potato.

E. REFERENCES

DER for MRID 46151701 DER for MRID 46151702

F. DOCUMENT TRACKING

RDI: RAB1 Chemists: 01/30/2008

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